

REMARKS

I. Election/Restriction of Invention

The Examiner has required restriction to one of the following inventions:

I. Claims 1-8, drawn to a dipeptide containing composition

II. Claims 9-11, drawn to an electrotransport delivery device utilizing the composition described in the Group I claims

III. A method of buffering a solution of a drug or electrolyte by using a dipeptide, as defined in the specifications, as the buffering agent.

The Applicants elect to continue prosecution with the invention described in Group I, claims 1-8, with traverse as provided herein.

A. Group I / Group II Restriction Improper

Applicants asserts that the restriction between Group I and Group II is improper. The Examiner has cited no support for the restriction between Group I and Group II, therefor the Applicants cannot respond to any particular justification for this restriction.

However, the Applicants assert that MPEP 806.05(c) Part II provides support for not restricting these two groups of claims. Section 806.05(c) Part II discusses restriction between an AB combination and claims directed to B alone. In this case, invention B, would be the formulation for transdermal electrotransport as provided in the Group I claims. The combination

AB (Group II) is an electrotransport device utilizing the formulation B (Group I) in a transdermal electrotransport drug delivery device.

The aforementioned MPEP section states “If there is no evidence that the combination AB_{sp} is patentable without the details of B_{sp}, restriction should not be required. Where the relationship between the claims is such that the separately claimed subcombination B_{sp} constitutes the essential distinguishing feature of the combination AB_{sp} as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the subcombination has separate utility.”

The claims in Group II, AB_{sp}, without the formulation is simply an electrotransport device which is well known in the art. The distinguishing feature is the formulation as provided for in Group I.

Therefor the restriction between Group I and Group II is not proper and should be withdrawn.

B. Restriction between Group I and III.

The Examiner has also required a restriction between Group I and Group III. Group I describes an electrotransport formulation and Group III claims have been amended to recite a method of making that formulation.

Applicants assert that this restriction is improper based upon the following arguments.

i. Improper Classification

Applicants assert that the Group III claims have been amended to recite a method of making the composition of Group I. The claims of Group III no longer recite a method of

buffering. Therefor the Examiner's reliance on MPEP § 806.05(h) is no longer proper. The claims now need to be evaluated based upon a Process of Making and Product Made criteria

Section 806.05(f) of the MPEP provides the basis upon which a set of claims reciting a product and a set of claims reciting a process of making the product

Applicants assert that the process *as claimed* is an obvious process of making the product. Also Applicants assert that the process *as claimed* cannot be used to making anything other than the claimed formulation.

In addition, the product as claimed cannot be made by another and materially different process.

Therefor not of criteria to support restriction based upon § 806.05(f) have been meet and a restriction between Group I and Group III is improper and should be withdrawn.

On page 3, paragraph 3 of the present office action, the Examiner references "Inventions II and II". Applicants assume the Examiner meant to refer to Inventions II and III and shall proceed with the following response based upon that assumption.

ii. Linking Claims

Applicants assert that § 809.03 of the MPEP provides a basis for retaining all three groups of claims.

Persuasive arguments have been provided for why Group I and II should not be restricted and why Groups I and III should not be restricted. Therefor it follows logically that Group I links together Group III, which is a method of making the formulation in Group I and Group II which is a combination of Group I and an electrotransport device.



II. Election of Species

In the drug genus, the Applicants elect the species hGH, human growth hormone and in the dipeptide genus elects the dipeptide Gly-His. All claims in elected Group I are readable on the elected species.

Respectfully submitted,

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